

1 Trenton H. Norris (CA Bar No. 164781)
trent.norris@hoganlovells.com
2 David M. Barnes (CA Bar No. 318547)
david.barnes@hoganlovells.com
3 Alexander Tablan (CA Bar No. 346309)
alexander.tablan@hoganlovells.com
4 HOGAN LOVELLS US LLP
5 Four Embarcadero Center, 35th Floor
San Francisco, CA 94111-4024
6 Telephone: 415.374.2300
Facsimile: 415.374.2499

7
8 GREGORY G. SPERLA (CA Bar No. 278062)
greg.sperla@dlapiper.com
9 DLA PIPER LLP
1415 L Street, Suite 270
10 Sacramento, CA 95814-3976
Telephone: 916.930.3200
11 Facsimile: 916.930.3201

12 Attorneys for Plaintiff
THE PERSONAL CARE PRODUCTS COUNCIL
13

14 **UNITED STATES DISTRICT COURT**
15 **EASTERN DISTRICT OF CALIFORNIA**
16

17 THE PERSONAL CARE
18 PRODUCTS COUNCIL,

19 Plaintiff,

20 v.

21 ROB BONTA, IN HIS OFFICIAL
22 CAPACITY AS ATTORNEY GENERAL
OF THE STATE OF CALIFORNIA,

23 Defendant.
24
25
26
27
28

Case No.

**COMPLAINT FOR DECLARATORY
AND INJUNCTIVE RELIEF**

1 Plaintiff The Personal Care Products Council (“Plaintiff” or “PCPC”) seeks prospective
2 declaratory and injunctive relief against Defendant Rob Bonta, in his official capacity as Attorney
3 General of the State of California, and alleges as follows:

4 **PRELIMINARY STATEMENT**

5 1. Plaintiff PCPC brings this suit to enjoin Defendant and those in privity with and acting
6 in concert with Defendant from enforcing in the future a requirement to provide a false, misleading,
7 and highly controversial cancer warning for cosmetic and personal care products that contain the
8 substance titanium dioxide (airborne, unbound particles of respirable size) (hereinafter, “Listed
9 Titanium Dioxide”).

10 2. Titanium dioxide is a mineral used as an ingredient in cosmetic and personal care
11 products, including color cosmetics (such as eye shadow, blush, foundation, setting powder, pressed
12 powder, loose powder, bronzer, and other makeup products), sunscreens, and toothpastes. It is
13 opaque (non-transparent), and its color is consistently bright white, allowing it to be mixed with other
14 pigments to create a varied palette of consistent shades. It is also used in foods, supplements, over-
15 the-counter and prescription medications, paints, coatings, and plastics.

16 3. Listed Titanium Dioxide is a subset of titanium dioxide, i.e., the form of titanium
17 dioxide that is composed of particles that are airborne, unbound, and of respirable size.

18 4. In 2010, the International Agency for Research on Cancer (“IARC”) published its
19 formal conclusion that titanium dioxide is “possibly carcinogenic to humans (Group 2B)” based on
20 “sufficient evidence in experimental animals for the carcinogenicity of titanium dioxide.” IARC
21 made its determination on the basis of two studies in which rats were exposed to titanium dioxide at
22 “lung overload” levels that are not relevant in humans and that have since been discredited. IARC
23 also concluded: “There is inadequate evidence in humans for the carcinogenicity of titanium
24 dioxide.” *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans* (Vol. 93), at 5.

25 5. As a result of the IARC determination, on September 2, 2011, California’s Office of
26 Environmental Health Hazard Assessment (“OEHHA”) listed “titanium dioxide (airborne, unbound
27 particles of respirable size)” as a chemical “known to the State to cause cancer” under California’s
28 Safe Drinking Water and Toxic Enforcement Act of 1986 (“Proposition 65”).

1 6. Under California law, OEHHA was required to list this form of titanium dioxide
2 without making its own independent scientific determination as to the carcinogenicity of the
3 substance. *Monsanto Co. v. Office of Env'tl. Health Hazard Assessment, et al.*, 22 Cal. App. 5th 534,
4 561 (2018). Indeed, no California agency has made any independent scientific determination as to
5 whether Listed Titanium Dioxide, much less the broader category of titanium dioxide, causes cancer
6 in humans. Nor has any other any regulatory agency anywhere in the world formally determined that
7 any form of titanium dioxide, including Listed Titanium Dioxide, causes cancer in humans.

8 7. The U.S. Food and Drug Administration ("FDA") has approved titanium dioxide as a
9 color additive that can be safely used in cosmetics, foods, and drugs, and as an active ingredient that
10 is safe and effective in sunscreen products, without regard to whether Listed Titanium Dioxide may
11 be present in the color additive or ingredient. FDA's position is consistent with those of regulators of
12 cosmetics, foods, and drugs in other countries, including Health Canada, Food Standards Australia
13 New Zealand, and the United Kingdom's Food Standards Agency.

14 8. Under Proposition 65, businesses are required to warn consumers about an exposure to
15 any substance that has been identified by OEHHA as "known to the State to cause cancer," unless an
16 exemption or affirmative defense to the warning requirement applies.

17 9. As a result of OEHHA's listing of Listed Titanium Dioxide, and despite scientific
18 studies showing that exposure to Listed Titanium Dioxide in cosmetic and personal care products
19 does not increase the risk of cancer in humans, businesses that manufacture, distribute, or sell
20 cosmetic and personal care products in California that contain Listed Titanium Dioxide are
21 presumptively required to provide a Proposition 65 cancer warning for their products. Businesses are
22 required to provide this message to consumers even though neither OEHHA nor any other
23 governmental entity has determined that Listed Titanium Dioxide is a known human carcinogen.

24 10. A Proposition 65 cancer warning for Listed Titanium Dioxide in cosmetic and
25 personal care products conveys to consumers the false and misleading message that using the
26 products will increase consumers' risk of cancer, even though there is no reliable evidence that
27 exposure to Listed Titanium Dioxide (or any form of titanium dioxide) in cosmetic and personal care
28 products increases the risk of cancer in humans.

1 11. California's presumptive requirement that businesses provide a Proposition 65 cancer
2 warning for cosmetic and personal care products that contain Listed Titanium Dioxide therefore
3 violates the First Amendment of the United States Constitution by compelling Plaintiff's members
4 and other entities that manufacture, distribute, or sell such cosmetic and personal care products to
5 make false, misleading, and highly controversial statements about their products.

6 12. In addition to being unconstitutional, California's treatment under Proposition 65 of
7 cosmetic and personal care products that contain Listed Titanium Dioxide harms both businesses and
8 the public. Businesses, including many of PCPC's members, must either take action to provide false,
9 misleading, and highly controversial warnings to California consumers about the safety of their
10 cosmetic and personal care products, or face potential costly enforcement actions initiated by
11 Defendant or private enforcers for failing to do so.

12 13. Members of the public, meanwhile, will be misled about the risks posed by cosmetic
13 and personal care products containing Listed Titanium Dioxide, or the broader category of titanium
14 dioxide, potentially frightening them away from using a variety of safe products or increasing their
15 anxiety about the risk of cancer from common household products.

16 14. Given the lack of reliable scientific evidence suggesting a causal relationship between
17 Listed Titanium Dioxide in cosmetic and personal care products and cancer risk, requiring cancer
18 warnings for Listed Titanium Dioxide in cosmetic and personal care products also will result in over-
19 warning, diluting the effectiveness of Proposition 65 warnings on other products that actually do pose
20 a risk of harm to consumers and diminishing consumers' confidence in public health messages and
21 the authorities who promulgate them.

22 15. For these reasons, with respect to Proposition 65 claims that are not currently pending
23 in state court and that concern Listed Titanium Dioxide in cosmetic and personal care products, the
24 Court should declare that mandating Proposition 65 cancer warnings for Listed Titanium Dioxide in
25 cosmetic and personal care products is unconstitutional under the First Amendment and enjoin
26 Defendant and those in privity with and/or acting in concert with Defendant (including
27 Proposition 65 private enforcers) from enforcing the Proposition 65 warning requirement as applied
28 to Listed Titanium Dioxide in cosmetic and personal care products.

PARTIES

16. Plaintiff The Personal Care Products Council is a nonprofit business association with a membership of approximately 600 businesses in the cosmetics industry. PCPC members supply ingredients for cosmetic and personal care products, manufacture cosmetic and personal care products, license their brands for use on cosmetic and personal care products, and sell cosmetic and personal care products in California and around the world. PCPC advocates for its members and the broader cosmetics and personal care industry before Congress and state and local legislative bodies, regulatory agencies, and courts. Because so many of its members are directly impacted by Proposition 65, PCPC has historically been and continues to be deeply involved in a variety of Proposition 65-related regulatory and litigation matters in addition to such matters related to other laws that regulate cosmetics and personal care products. Specifically, PCPC has coordinated and spearheaded policy discussions on Proposition 65 and cosmetic/personal care product issues involving business leaders, policy makers, scientists, and advocacy groups in both regulatory and legislative forums. PCPC has also closely monitored proposed listings of chemicals and other regulatory activities under Proposition 65, has advised its members on these issues, and has represented its members in policy discussions where the cosmetic industry may be affected.

17. Defendant Rob Bonta is the Attorney General of the State of California and the highest-ranking officer in the California Department of Justice. Attorney General Bonta is sued in his official capacity. He performs his official duties in Sacramento and throughout the State of California. As Attorney General, he is specifically empowered to enforce the provisions of Proposition 65 and to defend challenges to the constitutionality of all state statutes and regulations, including Proposition 65 and its implementing regulations.

JURISDICTION AND VENUE

18. This Court has jurisdiction over this action under 28 U.S.C. § 1331, which confers original jurisdiction on federal district courts over actions arising under the Constitution or laws of the United States.

19. Venue is proper under 28 U.S.C. § 1391(b)(1) and (b)(2), because the Attorney General is located within this district and a substantial part of the events giving rise to Plaintiff's

claims occurred in this district.

FACTUAL BACKGROUND

A. Overview of Titanium Dioxide in Cosmetic and Personal Care Products

20. FDA regulations state: “The color additive titanium dioxide may be safely used in cosmetics” 21 C.F.R. § 73.2575(b).

21. FDA’s determination that the use of titanium dioxide as a color additive in cosmetics is safe was based on consideration of the factors set out in Section 721 of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 379e(b)(5)(A), including:

(i) “the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs or devices, or cosmetics because of the use of the additive; . . .

(iii) “safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

(iv) “the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food drug or device, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.”

22. FDA regulations further provide that titanium dioxide may be safely used as a color additive in “cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.” 21 C.F.R. § 73.2575(b). FDA applies stringent standards for use of cosmetic ingredients in the area of the eye, requiring that any listing or certification of a color additive must “specifically provide” for its use in products intended for the area of the eye, and that if the certification or listing does not so provide, it shall not be considered to authorize use in these types of products. 21 C.F.R. § 70.5(a); *see also* FDA, Eye Cosmetic Safety, <https://www.fda.gov/cosmetics/cosmetic-products/eye-cosmetic-safety> (visited May 17, 2023) (“In the United States, the use of color additives is strictly regulated. A number of color additives

approved for cosmetic use in general are not approved for use in the area of the eye.”).

23. FDA has approved titanium dioxide for use in sunscreen. FDA has included titanium dioxide in its list of permissible active ingredients for sunscreens since 1999, which was confirmed in a final administrative order pursuant to the 2020 Coronavirus Aid, Relief, and Economic Security Act (CARES Act). *See* 21 C.F.R. § 352.10 (listing titanium dioxide as an active ingredient in sunscreens); 21 U.S.C. § 355h(a)(2) (adopting the requirements of 21 C.F.R. § 352.10); *see also* Final Administrative Order (OTC000006) Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use (Sept. 24, 2021), at § M020.10(n).

24. To the extent that Listed Titanium Dioxide may be contained in titanium dioxide, titanium dioxide is still considered approved for use in cosmetics and sunscreens by FDA.

25. FDA has also approved the use of titanium dioxide as a color additive in foods, including supplements, 21 C.F.R. § 73.575; and in drugs, including over-the-counter drugs. *Id.* § 73.1575. FDA’s determination that titanium dioxide is safe when used as a color additive in foods was made on the basis of its finding that such use will not “induce cancer when ingested by man or animal.” 21 U.S.C. § 379e(b)(5)(B).

26. Titanium dioxide is a recognized cosmetic ingredient listed in the International Cosmetic Ingredient Dictionary and Handbook, which is the authoritative source that FDA directs cosmetic companies to use in designating ingredients on cosmetic labels. 21 C.F.R. § 701.3. Like all ingredients in cosmetics (other than fragrances or flavors), titanium dioxide must be listed on the label of each package. *Id.*

27. Titanium dioxide has been used widely in cosmetic products for decades. Under its Safe Cosmetics Program, the State of California requires manufacturers of cosmetic products to report those that contain titanium dioxide and other ingredients. California makes this information available to the public in the form of the California Safe Cosmetics Program Product Database, which can be searched online at <https://cscpsearch.cdph.ca.gov/search/publicsearch>. As of May 26, 2023, that database identifies 94,216 cosmetic products that are reported to contain titanium dioxide or Listed Titanium Dioxide.

28. Titanium dioxide has numerous useful properties. Because of its consistent bright

white color, it gives intensity and brightness to other colors and provides a base for consistent shades that suit all skin types. Its opaque qualities are critical in concealing blemishes. It also helps soak up oils in the skin and reduces shine. It is long-lasting and waterproof, and it is attractive to many consumers because of its mineral base. Titanium dioxide is also useful in the development of products for people with sensitive skin.

29. Private enforcers of Proposition 65 have contended that hundreds of cosmetic and personal care products that disclose titanium dioxide as an ingredient also contain Listed Titanium Dioxide.

30. Determining whether a product contains the specific form of Listed Titanium Dioxide as a factual, scientific matter requires expert testing, analysis, and testimony and is subject to dispute. First is the question of whether the titanium dioxide in the product contains particles of respirable size. The term “respirable size” is not defined in the listing for Listed Titanium Dioxide or in other guidance from OEHHA that is directly applicable. For other chemicals that OEHHA has listed using the term “respirable size,” OEHHA has relied on IARC for the definition of “respirable size” as “that fraction of an aerosol with an aerodynamic diameter suitable for penetration into the alveoli/gas exchange region of the lung (typically <10 µm).” See OEHHA, *Chemical Listed Effective February 21, 2003 as Known to the State of California to Cause Cancer: Carbon Black (airborne, unbound particles of respirable size)*, available at <https://oehha.ca.gov/proposition-65/cmr/chemical-listed-effective-february-21-2003-known-state-california-cause-cancer> (visited May 17, 2023). In addition to the potential for disputes about this ambiguous term, microscopic analysis of products is necessary to determine whether they contain any particles of this size.

31. Second, determining whether any particles are “airborne” in ordinary use requires simulation of common usage scenarios under varying conditions (e.g., indoors at home, while traveling in a motor vehicle or on public transit, indoors in a public restroom or at one’s desk, etc.). There is considerable ambiguity and variability around this term as well.

32. And third, there is no regulatory or scientific definition of the term “unbound” that describes the particles that form Listed Titanium Dioxide. As a result, manufacturers and retailers of cosmetic products that contain titanium dioxide face great uncertainty in litigation as to how a court

will apply the term “unbound” to the titanium dioxide in their products, and they have no reliable standard by which to conform their conduct, seek assurances from suppliers, or ensure that their products do not contain Listed Titanium Dioxide.

33. The ambiguity surrounding the determination of whether Listed Titanium Dioxide—the regulated chemical—is present in a product means that virtually any manufacturer of a cosmetic or personal care product that identifies “titanium dioxide” on its label is at risk of being sued based on the allegation that some portion of that ingredient is in the form of Listed Titanium Dioxide. Because the plaintiff in a Proposition 65 enforcement action need only identify the listed chemical and a plausible means of exposure in order to shift the burden of proof to the defendant(s), manufacturers of almost 100,000 different cosmetic and personal care products sold in California are at risk of expensive, time-consuming, and uncertain litigation due to the Proposition 65 warning requirement for Listed Titanium Dioxide.

B. No Valid Toxicological or Epidemiological Studies Demonstrate That Titanium Dioxide, in Any Form, Increases the Risk of Cancer in Humans

34. Current scientific evidence does not support a finding that exposure to Listed Titanium Dioxide from cosmetic or personal care products increases the risk of cancer in humans. Both the toxicological studies in rats that led to IARC’s determination that titanium dioxide is “possibly carcinogenic to humans”—and therefore to OEHHA’s listing—are widely considered to be unreliable and unacceptable. That is because they subjected the rats to conditions of “lung overload” that are implausible in humans due to the unrealistically high quantities of airborne titanium dioxide used on the rats, the far greater surface area of human lungs, and the far greater capacity of humans, as opposed to rats, to clear their lungs. Furthermore, there is no reliable epidemiological evidence that inhaled titanium dioxide causes cancer in humans. On the contrary, the overwhelming weight of evidence indicates that titanium dioxide is not carcinogenic to humans, even at the highest observed levels of exposure.

35. IARC’s classification of titanium dioxide as “possibly carcinogenic to humans” is based on two studies of inhalation in rats:

(a) K.P. Lee, et al., *Pulmonary response of rats exposed to titanium dioxide (TiO₂) by*

1 *inhalation for two years*, 79 *Toxicology and Applied Pharmacology* 179-92 (1985); and
2 (b) U. Heinrich, et al., *Chronic Inhalation Exposure of Wistar Rats and two Different Strains*
3 *of Mice to Diesel Engine Exhaust, Carbon Black, and Titanium Dioxide*, 7 *Inhalation*
4 *Toxicology* 533-56 (1995).

5 36. Both of these studies have been discredited as evidence suggesting carcinogenicity of
6 titanium dioxide, not only in the eyes of independent and experienced scientists, but also in official
7 proceedings in the European Union. The authors of the first study by Lee et al. expressly cautioned
8 against a finding of carcinogenicity of titanium dioxide, writing that “the biological relevance” of the
9 tumors shown in the rats in his study “is negligible.” Lee, et al., at 179.

10 37. In 2017, the Committee for Risk Assessment (RAC) of the European Chemical
11 Agency (ECHA) considered the Lee et al. (1985) study and determined that it was not a “reliable and
12 acceptable” study because the doses of airborne titanium dioxide to which the rats were subjected
13 were excessive and caused the rats to experience lung overload. *Opinion proposing harmonized*
14 *classification and labelling at EU level of Titanium dioxide*, CLH-O-0000001412-86-163/F (Sept. 14,
15 2017), at 34 (“RAC takes the view that this marked condition of overload should not have a
16 determining influence on classification of TiO₂.”), 39 (“RAC takes the view, that these exposure
17 conditions represent excessive exposure which invalidates the results of the Lee et al. (1985) study on
18 their own for classification purposes.”).

19 38. Lung overload (or particle overload) is a term that describes conditions under which
20 the excessive amount of particulate matter overwhelms the mechanisms that a subject animal has for
21 clearing its lungs. This leads to chronic inflammation, fibrosis, and ultimately—in some species
22 (rats) but not all—tumors.

23 39. Humans have much more effective mechanisms for clearing particles from their lungs
24 than do rats, meaning that the conditions that will cause lung overload in rats will not cause lung
25 overload in humans. For example, humans have far more pulmonary macrophages, which act to clear
26 foreign matter from the deep region of the lungs. In addition, under ordinary conditions that lack
27 artificial constraints (such as those imposed on laboratory animals in studies), humans are very likely
28 to avoid exposures that may lead to lung overload. As a result, lung overload in humans is highly

1 unlikely. Furthermore, there is no evidence that lung overload, even if it does occur, causes cancer in
2 humans.

3 40. The ECHA RAC in 2017 accepted the other study on which the IARC classification is
4 based: Heinrich et al. (1995). The ECHA RAC relied on this study for its opinion that titanium
5 dioxide is a category 2 carcinogen, especially when exposure occurs via inhalation and in powder
6 form containing 1 percent or more of particles of a diameter equal to or below 10 micrometers. On
7 the basis of the ECHA RAC opinion, in October 2019, the European Commission adopted Regulation
8 2020/217, by which it proceeded with the harmonized classification and labeling of titanium dioxide,
9 recognizing that it was suspected of being carcinogenic to humans, by inhalation, in powder form
10 containing 1% or more of particles of an aerodynamic diameter equal to or below 10 micrometers.

11 41. But in November 2022, the General Court of the European Court of Justice annulled
12 Regulation 2020/217 as it applied to inhalable forms of titanium dioxide, ruling that the European
13 Commission “made a manifest error in its assessment of the reliability and acceptability of the study
14 on which the classification was based,” namely, the Heinrich (1995) study. The General Court ruled
15 that “the RAC’s findings that the lung overload in the [Heinrich] study at issue was acceptable were
16 implausible.” Accordingly, the second study that prompted the IARC classification, and therefore the
17 consequent OEHHA listing of Listed Titanium Dioxide, is invalid.

18 42. The General Court of the European Court of Justice annulled Regulation 2020/217 on
19 a second basis as well, namely that the ECHA RAC Opinion incorrectly determined that titanium
20 dioxide “has the intrinsic property to cause cancer.” The General Court found that: “The
21 carcinogenicity hazard is linked solely to certain respirable titanium dioxide particles, when they are
22 present in a certain form, physical state, size and quantity, it occurs only in lung overload conditions
23 and corresponds to particle toxicity.” In other words, the General Court ruled that titanium dioxide
24 does not have “the intrinsic property to cause cancer” but instead only causes cancer in rats under
25 conditions of lung overload. It therefore held that the European Commission “committed a manifest
26 error of assessment” in classifying inhaled forms of titanium dioxide as carcinogenic.

27 43. IARC’s classification of titanium dioxide as a possible human carcinogen was
28 therefore based on two studies that have been found to be unreliable and unacceptable by official

1 authorities of the European Union. OEHHA's listing of Listed Titanium Dioxide is based solely on
2 the IARC classification.

3 44. IARC's classification was based solely on animal studies, and it expressly found:
4 "There is inadequate evidence in humans for the carcinogenicity of titanium dioxide." See ¶ 4, *supra*.
5 IARC stated in more detail: "In summary, the [epidemiological] studies do not suggest an
6 association between occupational exposure to titanium dioxide as it occurred in recent decades in
7 western Europe and North America and risk for cancer." In other words, there is no reliable
8 epidemiological evidence that inhaled titanium dioxide causes cancer in humans.

9 C. Proposition 65 Regulatory Framework

10 45. In 1986, California voters, by initiative, enacted the Safe Drinking Water and Toxic
11 Enforcement Act of 1986—commonly known as Proposition 65. In relevant part, Proposition 65
12 prohibits businesses with ten or more employees from knowingly and intentionally exposing
13 California residents to a chemical known to the State to cause cancer without providing required
14 warnings, unless an exemption or affirmative defense applies. Cal. Health & Safety Code
15 §§ 25249.6, 25249.10.

16 46. Proposition 65 requires OEHHA to maintain "a list of those chemicals known to the
17 state to cause cancer or reproductive toxicity" and provides mechanisms by which OEHHA may (or
18 must) place a chemical on the list. *Id.* §§ 25249.8(a)-(b).

19 47. As relevant here, the statute provides that the list "shall include at a minimum those
20 substances identified by reference in Labor Code Section 6382(b)(1) and those substances identified
21 additionally by reference in Labor Code Section 6382(d)." Cal. Health & Safety Code § 25249.8(a).
22 Those Labor Code sections refer, by cross-reference, to classifications by IARC. As a result, once
23 IARC determines that a chemical is at least a possible human carcinogen with sufficient evidence in
24 animals, OEHHA lists it as "known to the state to cause cancer." 27 Cal. Code Regs. § 25904(b)(3).
25 OEHHA has no discretion; the listing is automatic. See *Monsanto*, 22 Cal. App. 5th at 561.

26 48. After a chemical is added to the Proposition 65 list, and following a 12-month grace
27 period, Proposition 65 requires that any "person in the course of doing business" provide a "clear and
28 reasonable warning" before "expos[ing] any individual to" the listed chemical, unless an exemption

1 or affirmative defense applies. Cal. Health & Safety Code § 25249.6.

2 49. Although Proposition 65 does not define what content suffices to convey a “clear and
3 reasonable warning,” OEHHA’s regulations had for more than 30 years provided that the warning
4 “must clearly communicate that the chemical in question is known to the state to cause cancer. . . .”
5 27 Cal. Code Regs. § 25601 (effective until Aug. 30, 2018). OEHHA also provided a “safe harbor”
6 for warnings that used the following language: “**WARNING:** This product contains a chemical
7 known to the State of California to cause cancer.” *Id.* § 25603.2 (effective until Aug. 30, 2018).

8 50. In August 2016, OEHHA adopted new regulations providing that safe harbor
9 Proposition 65 warnings must provide consumers with additional information.

10 51. Under the new warning regulations, cancer warnings for cosmetic products are
11 deemed to be “clear and reasonable” if they state: “**WARNING:** This product can expose you to
12 [name of chemical], which is known to the State of California to cause cancer. For more information,
13 go to www.P65Warnings.ca.gov.” 27 Cal. Code Regs. § 25603(a)(2)(A). Alternatively, the warning
14 can be provided in a short form with the following preceded by a yellow triangle symbol:
15 “**WARNING:** Cancer – www.P65Warnings.ca.gov.”

16 52. Proposition 65 provides a statutory exemption to the warning requirement, which can
17 be asserted as an affirmative defense in a Proposition 65 enforcement action, if “the person
18 responsible can show that the exposure poses no significant risk assuming lifetime exposure at the
19 level in question for substances known to the state to cause cancer.” Cal Health & Safety Code
20 § 25249.10(c). This threshold is commonly referred to as the “No Significant Risk Level” (“NSRL”).
21 The NSRL is not a concentration limit, but rather an exposure-based limit based on the highest level
22 of exposure causing no more than a 1 in 100,000 risk of cancer over a lifetime of exposure to that
23 level. Cal. Health & Safety Code § 25249.10(c); 27 Cal. Code Regs. § 25703(b).

24 53. For some listed substances, OEHHA has published a quantitative NSRL, often
25 referred to as a “safe harbor” NSRL because it is a presumptive NSRL such that a private enforcer
26 cannot argue for a more stringent NSRL in litigation. 27 Cal. Code Regs. § 25705. A safe harbor
27 NSRL is also an exposure-based limit. All safe harbor NSRLs for listed chemicals are described in
28 micrograms of exposure per day. *Id.* OEHHA has not promulgated a safe harbor NSRL for Listed

1 Titanium Dioxide. As a result, in an enforcement action, the defendant business must first establish,
2 through scientific testimony, what the appropriate NSRL is for Listed Titanium Dioxide.

3 54. Under Proposition 65, to determine whether an exposure from a consumer product
4 exceeds the NSRL (once it is established), the regulations require that exposures be calculated based
5 on the “average rate of intake or exposure for average users of the consumer product.” 27 Cal. Code
6 Regs. § 25721(d)(4). Thus, unlike other laws and regulations affecting businesses that set
7 concentration-based thresholds, it is not facially apparent from the NSRL described in the statute or
8 from a safe harbor NSRL adopted by OEHHA and listed in the regulations whether there is a duty to
9 warn under Proposition 65.

10 55. Under the statute, it is the burden of a business to demonstrate that the exposure at
11 issue does not exceed the NSRL. OEHHA has not provided any guidance concerning analytical
12 methods or testing procedures to determine exposure levels to Listed Titanium Dioxide.

13 56. In addition, the NSRL provides only an “affirmative defense” to liability under
14 Proposition 65 and does not immunize industry from enforcement actions in the first instance. *See*
15 *DiPirro v. Bondo Corp.*, 153 Cal. App. 4th 150, 185 (2007).

16 57. Courts have found that no warning is required where a business can demonstrate that
17 exposures to the chemical do not pose a significant risk of cancer at *any* level. In *Baxter Healthcare*
18 *Corporation v. Denton*, 120 Cal. App. 4th 333 (2004), the California Court of Appeal held that “a
19 warning is not required if . . . the exposure poses no significant risk of causing cancer in humans.”
20 *Id.* at 343-44. The court determined that the chemical at issue in that case (DEHP) does not cause
21 cancer in humans and therefore no warning was required, even though the court found that the
22 chemical was properly listed and DEHP remains on the list today. Importantly, however, the court
23 explained that the business bore the burden of proof to establish that exposure to DEHP presented no
24 significant risk of cancer in humans. *Id.* at 364-69.

25 **D. Enforcement of Proposition 65**

26 58. Proposition 65 employs an unusual enforcement scheme. First, the Attorney General,
27 a district attorney, or a variety of local government officials may bring an enforcement action under
28 Cal. Health & Safety Code § 25249.7(c). The statute imposes penalties up to \$2,500 per day for each

violation. *Id.* § 25249.7(b). In addition to these penalties, the statute also provides that any person who “threatens to violate” the warning requirement may be “enjoined in a court of competent jurisdiction.” *Id.* § 25249.7(a).

59. Second, any *person* (even one who has suffered no injury in fact) may bring a private enforcement action for an alleged failure to provide an adequate warning and without having to plead or prove injury or harm. *Id.* § 25249.7(d). These private enforcers are eligible to recover 25 percent of the penalty (with the remaining 75 percent going to the State of California’s Safe Drinking Water and Toxic Enforcement Fund in the State Treasury), *id.* § 25249.12, as well as their reasonable attorneys’ fees and costs, Cal. Code Civ. Proc. § 1021.5, creating very strong incentives for private enforcement. Defendants usually cannot remove these enforcement actions to federal court because the plaintiff has no Article III standing.

60. Private parties are required to provide 60-days’ notice—to the California Attorney General, the district attorney, city attorney, or prosecutor in whose jurisdiction the violation is alleged to have occurred, and to the alleged violator—before initiating an enforcement action. *See* Cal. Health & Safety Code § 25249.7(d)(1). If, after 60 days, “[n]either the Attorney General, a district attorney, a city attorney, nor a prosecutor has commenced and is diligently prosecuting an action against the violation,” the private enforcer may bring an action in state court. *Id.* § 25249.7(d)(2). The Attorney General also is authorized to review proposed settlements in enforcement actions initiated by private enforcers and to challenge a proposed settlement that is not in the public interest. *Id.* § 25249.7(f); Cal. Code Regs. tit. 11, § 3003(a).

61. The private enforcement mechanism of Proposition 65 is unique and allows any person or law firm to act as a private enforcer to prosecute alleged violations of the Act. Courts and commentators have recognized the widescale abuse of Proposition 65 through private enforcement actions. *See, e.g.,* Anthony T. Caso, *Bounty Hunters and the Public Interest—A Study of California Proposition 65*, 13 Engage 30, 31 (Mar. 2012) (describing case in which “law firm created an ‘astroturf’ environmental group to be a plaintiff in Proposition 65 litigation,” which group “consisted of partners from the law firm” and which “sent out hundreds of demand letters charging businesses with failure to provide warnings” and “extort[ing] payments of attorney fees or contributions to the

front group”).

62. Significantly, private enforcement actions are pervasive even for chemicals for which OEHHHA has adopted a “safe harbor” NSRL. Even where OEHHHA has adopted a safe harbor NSRL, the defendant still bears the burden under the statute of establishing as an affirmative defense that any exposures fall within the safe harbor. Cal. Health & Safety Code § 25249.10(c). In alleging an exposure to a listed chemical, a private enforcer is not required to prove that an exposure exceeds the NSRL. *Consumer Cause, Inc. v. SmileCare*, 91 Cal. App. 4th 454, 474 (2001). Instead, under the statute, the burden to prove that the exposure *does not* exceed the NSRL rests with the defendant business. And proving this negative in court is a costly and time-consuming endeavor, typically requiring expert testimony and evidence. *See, e.g., Env'tl. Law Found. v. Beech-Nut Nutrition Corp.*, 235 Cal. App. 4th 307, 314 (2015) (safe harbor defense litigated at trial); *Council for Educ. & Research on Toxics v. Starbucks Corp.*, No. BC435759 (Cal. Super. Ct., June 2, 2017) (rejecting Starbucks’s “no significant risk level” defense at summary judgment). In other words, a safe harbor NSRL does not effectively deter a private enforcer with significant financial incentives from initiating suit in the hopes of collecting a settlement.

63. But where OEHHHA has not adopted a “safe harbor” NSRL, as with Listed Titanium Dioxide, the burdens on the defendant in an enforcement action are multiplied. First, the defendant must establish, with extensive scientific testimony, by a preponderance of the evidence, what the appropriate NSRL for Listed Titanium Dioxide is. And then, the defendant must establish that its products, in ordinary use and on average, expose consumers to less than the NSRL.

64. California jurists have recognized how onerous private enforcement suits can be for industry. “[L]awsuits under Proposition 65 can be filed and prosecuted by any person against any business based on bare *allegations* of a violation unsupported by any evidence of an actual violation—or even a good faith belief that a defendant is using an unsafe amount of a chemical known by the state to cause cancer.” *SmileCare*, 91 Cal. App. 4th at 477 (Vogel, J., dissenting) (emphasis in original). This burden-shifting regime results in “judicial extortion” where many private parties bring Proposition 65 claims (without an appropriate assessment that an exposure exceeds the NSRL) and force the defendant to settle to avoid legal fees and the costs of performing

1 an expensive expert scientific assessment. *Id.* at 477-79.

2 65. Thus, in practice, businesses faced with the threat of costly litigation to prove a
 3 defense to the warning requirement often are forced to acquiesce and provide a warning, regardless of
 4 whether the businesses know the warning is affirmatively false or misleading. *See* All. for Nat.
 5 Health, *PROPOSITION 65: Evaluating Effectiveness and a Call for Reform*, at 7, [https://www.anh-](https://www.anh-usa.org/wp-content/uploads/2015/09/Prop-65.pdf)
 6 [usa.org/wp-content/uploads/2015/09/Prop-65.pdf](https://www.anh-usa.org/wp-content/uploads/2015/09/Prop-65.pdf) (last visited May 25, 2023); *see also* LATIMES,
 7 *Warning: Too Many Warnings Signs are Bad for Your Health* (Sept. 30, 2017) (noting “Starbucks,
 8 Whole Foods and about 80 other places in California that sell coffee” are exposed under
 9 Proposition 65 even though “research increasingly” indicates coffee does *not* cause cancer),
 10 [https://www.latimes.com/opinion/editorials/la-ed-proposition-65-warning-coffee-20170930-](https://www.latimes.com/opinion/editorials/la-ed-proposition-65-warning-coffee-20170930-story.html)
 11 [story.html](https://www.latimes.com/opinion/editorials/la-ed-proposition-65-warning-coffee-20170930-story.html) (last visited May 25, 2023); Richard Berman, *Thanks to a Poorly-Designed Law,*
 12 *California Classifies Soft Drinks as a Cancer Risk*, *Forbes* (Feb. 20, 2014) (compelling warnings for
 13 soda drinks on the basis that if consumers drink “over 1,000 sodas a day” they would have increased
 14 cancer risk), [https://www.forbes.com/sites/realspin/2014/02/20/thanks-to-a-poorly-designed-law-](https://www.forbes.com/sites/realspin/2014/02/20/thanks-to-a-poorly-designed-law-california-classifies-soft-drinks-as-a-cancer-risk/?sh=49d6eb0eb8c1)
 15 [california-classifies-soft-drinks-as-a-cancer-risk/?sh=49d6eb0eb8c1](https://www.forbes.com/sites/realspin/2014/02/20/thanks-to-a-poorly-designed-law-california-classifies-soft-drinks-as-a-cancer-risk/?sh=49d6eb0eb8c1) (last visited May 25, 2023);
 16 Greg Ryan, *Rice Sellers Threatened with Prop 65 Suits over Lead, Arsenic*, *Law360* (Feb. 20, 2014),
 17 <https://www.law360.com/articles/511743/rice-sellers-threatened-with-prop-65-suits-over-lead-arsenic>
 18 (last visited May 25, 2023).

19 **E. Proposition 65 Listing of Listed Titanium Dioxide and Subsequent Enforcement**
 20 **Actions**

21 66. OEHHA added Listed Titanium Dioxide to the Proposition 65 list of carcinogens on
 22 September 2, 2011. The listing became effective on September 2, 2012.

23 67. The first Proposition 65 notice of violation based on Listed Titanium Dioxide in
 24 cosmetic products came within six months, and hundreds more have followed.

25 68. The first set of notices, which were dated February 15 and April 12, 2013, named 10
 26 manufacturers and three retailers of spray sunscreens. These resulted in no reported litigation or
 27 settlements. The private enforcer on these notices was Center for Environmental Health.

28 69. The second set of notices, which were dated June 12 and June 24, 2013, named

1 approximately 135 manufacturers of color cosmetic products. According to the Attorney General's
2 database of Proposition 65 private enforcement actions, these notices resulted in settlement payments
3 of \$826,500 (\$100,000 in civil penalties and \$726,500 in attorney fees) by over 60 companies. Many
4 of the settling companies agreed to stop selling products in California that contain Listed Titanium
5 Dioxide. The private enforcer on these notices was Public Interest Alliance LLC.

6 70. The second set of notices resulted in litigation with the remaining half of the noticed
7 manufacturers who did not settle. After more than a year of expensive litigation, including fact and
8 expert discovery, the Alameda Superior Court granted summary judgment against Public Interest
9 Alliance based on its inability to prove, as a scientific matter, that any amount of Listed Titanium
10 Dioxide was indeed present in the products. *See* Order Granting Summary Judgment in *Public*
11 *Interest Alliance LLC v. Access Business Group, LLC*, Alameda Superior Court Case No.
12 RG13697992 (July 28, 2015).

13 71. More than five years passed before the next Proposition 65 notice of violation on
14 Listed Titanium Dioxide in cosmetics. On December 2, 2020, a private enforcer named Piyush
15 Yadav issued notices to seven manufacturers of color cosmetics. One settled for a total payment of
16 \$20,000. There is no record of settlement with the other parties.

17 72. Then, on July 7, 2021, a new round of notices of violation began, continuing to this
18 day. This round includes over 350 notices of violation to manufacturers and retailers of color
19 cosmetics alleging failure to warn of exposure to Listed Titanium Dioxide issued by four private
20 enforcers: Piyush Yadav, Environmental Health Advocates, Ecological Alliance LLC, and Esther
21 Espinoza. Approximately one dozen companies have settled these charges for a total of \$49,100 in
22 civil penalties and \$501,400 in attorney fees payments.

23 73. These notices have resulted in at least 110 lawsuits filed in five different counties'
24 Superior Courts. On May 3, 2023, defendants in several of these lawsuits filed a petition with the
25 statewide Judicial Council to coordinate 108 Proposition 65 enforcement actions on Listed Titanium
26 Dioxide and refer them to one judge for resolution of pre-trial issues, including the controversial
27 technical and scientific issues raised by the complaint in each of these lawsuits. *See* Judicial Council
28 Coordination Petition No. 5285. That petition is pending.

1 74. The pending notices and lawsuits on Listed Titanium Dioxide include alleged
2 violations related to powder products such as blush, eyeshadow, foundation, brow powder, loose
3 powder, and bronzer.

4 75. Notably, although Listed Titanium Dioxide has been on the Proposition 65 list for
5 more than a decade, the number of companies named in 60-day notices has increased exponentially in
6 recent years, going from only 7 companies in 2020; to 15 companies in 2021; to 211 companies in
7 2022; and 127 companies noticed so far in 2023.

8 76. As noted, many of these 60-day notices have resulted in lawsuits or settlements, and
9 there is a real and credible threat that other companies are likely to be future targets of Proposition 65
10 litigation related to alleged exposures to Listed Titanium Dioxide in cosmetic products.

11 77. Although there have been numerous Proposition 65 lawsuits in state court concerning
12 Listed Titanium Dioxide in cosmetic products—and although many of the defendant businesses in
13 those cases have asserted the First Amendment as an affirmative defense in their responsive
14 pleadings—the First Amendment issue presented by this Complaint has not been considered in state
15 courts. This is driven by Proposition 65’s enforcement structure: a business faced with the threat of
16 costly litigation and civil penalties has overwhelming economic incentives to acquiesce and settle,
17 regardless of whether the business believes the warning is false or misleading. Few companies are
18 able to accept the risk of litigating a Proposition 65 enforcement action through trial while incurring
19 significant legal fees to do so.

20 78. In fact, the First Amendment issue has been litigated only twice in state court
21 enforcement actions, and only once on the merits:

22 a. The first case in 2008—*People v. Frito-Lay, Inc., et al.* (Los Angeles County
23 Sup. Ct., No. BC 338956)—involved allegations the chemical acrylamide in snack foods requires a
24 Proposition 65 cancer warning. The California Superior Court denied the defendant businesses’
25 motion for summary judgment and the Attorney General’s cross-motion for summary adjudication on
26 First Amendment grounds, finding that there was a triable issue of material fact. Facing the risk and
27 expense of trial, the defendants in that lawsuit subsequently settled, and therefore the Superior Court
28 never issued a ruling on the merits of the businesses’ First Amendment defense.

b. The second case—*Council for Education & Research on Toxics v. Starbucks, et al.* (Los Angeles County Sup. Ct., No. BC 435759)—also involved allegations the chemical acrylamide requires a Proposition 65 cancer warning, this time in coffee. The California Superior Court ruled after the first phase of trial that certain of the defendants failed to meet their burden to show that compelling a cancer warning on coffee products violated their First Amendment rights. But the California Court of Appeal did not consider the merits of the First Amendment issue in the *Starbucks* case and instead resolved the case on non-constitutional grounds without any need for consideration of the First Amendment issue.

ADVERSE IMPACTS TO PLAINTIFF, ITS MEMBERS, AND THE PUBLIC

79. If not prospectively enjoined, the Proposition 65 warning requirement for chemicals listed as “known to the State of California to cause cancer,” as applied to Listed Titanium Dioxide in cosmetic and personal care products, will have an immediate and irreversible impact on Plaintiff, its members, and the public.

80. Since 2013, more than 400 companies, including many of Plaintiff’s members that sell cosmetic and personal care products, have been targeted with 60-day pre-litigation notices in connection with alleged exposures to Listed Titanium Dioxide in their products. Many of Plaintiff’s members also have been sued in connection with these 60-day notices. Indeed, several of the companies represented on Plaintiff’s Board of Directors have received 60-day notices on Listed Titanium Dioxide in their products and been sued in connection with such notices.

81. At the same time, due to the widespread (and FDA-permitted) presence of titanium dioxide in almost 100,000 cosmetic and personal care products sold in California, many of Plaintiff’s members that sell or manufacture products that are sold in California have not yet been sued under Proposition 65 in connection with some, or all, of their products whose ingredient lists bear the name titanium dioxide. Because of California’s listing of Listed Titanium Dioxide and the attendant Proposition 65 warning requirement, these members must either take action, in conjunction with their distributors and customers, to provide false, misleading, and factually controversial warnings to California consumers about Listed Titanium Dioxide in their products—conveying the unsubstantiated message that Listed Titanium Dioxide in cosmetic products increases cancer risk in

1 humans—or face a significant and imminent risk of an enforcement action seeking substantial civil
2 penalties and attorneys’ fees for failing to do so.

3 82. Alternatively, Plaintiff’s many members that have not yet been sued may be forced to
4 undertake costly exposure assessments for their titanium dioxide-containing products to demonstrate
5 that any exposures to Listed Titanium Dioxide from their products do not exceed the NSRL and do
6 not require warnings. And even if Plaintiff’s members’ assessments indicate that exposures to Listed
7 Titanium Dioxide from their products do not exceed the NSRL, they still would need to prepare to
8 defend against likely enforcement actions by private enforcers. Private enforcers are not required to
9 defer to a company’s exposure assessment and may dispute the exposure assessment. Thus, a
10 company that wishes to defend its exposure assessment and to prove that an exposure does not
11 exceed the NSRL faces the prospect of costly and risky litigation on a technical and expert-heavy
12 defense.

13 83. The requirement to place a false, misleading, and highly controversial Proposition 65
14 cancer warning for Listed Titanium Dioxide on cosmetic and personal care products has had, and will
15 continue to have, a substantial adverse impact on Plaintiff’s members. Such a warning disparages
16 Plaintiff’s members and their products by creating the false impression among consumers that those
17 products are unsafe and increase human cancer risk, despite scientific evidence suggesting that Listed
18 Titanium Dioxide in cosmetic and personal care products does not increase the risk of cancer in
19 humans.

20 84. Applying a false, misleading, and highly controversial Proposition 65 cancer warning
21 on cosmetic and personal care products also would have a substantial adverse impact on the public.

22 85. First, a Proposition 65 cancer warning for Listed Titanium Dioxide in cosmetic and
23 personal care products would mislead consumers about the human health risks posed by cosmetic
24 products containing Listed Titanium Dioxide as well as titanium dioxide and frighten consumers
25 away from safe cosmetic products.

26 86. Furthermore, requiring businesses to apply a Proposition 65 cancer warning for Listed
27 Titanium Dioxide in cosmetic and personal care products, despite the lack of reliable scientific
28 evidence supporting a finding that Listed Titanium Dioxide from cosmetic products increases human

cancer risk, dilutes the effectiveness of legitimate Proposition 65 warnings. *See, e.g.*, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §2 cmt. j (1998) (noting that excessive, multitudinous warnings “may be ignored by users and consumers and may diminish the significance of warnings about [other] risks” and “could reduce the efficacy of warnings generally.”); *Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652, 661 (1991) (“[U]nnecessary warnings . . . could distract the public from other important warnings on consumer products.’ Since one of the principal purposes of [Proposition 65] is to provide ‘clear and reasonable warning’ of exposure to carcinogens and reproductive toxins, such warnings would be diluted to the point of meaninglessness if they were to be found on most or all food products.”) (quoting the Final Statement of Reasons for the “naturally occurring” regulation now found at CAL. CODE REGS. tit. 27, §25501)); *accord Johnson v. Am. Standard, Inc.*, 43 Cal. 4th 56, 70 (2008) (quoting *Finn v. G.D. Searle & Co.*, 35 Cal. 3d 691, 701 (1984)).

87. Indeed, the California Supreme Court in another context has recognized that excessive warnings “produce a cacophony . . . that by reason of their sheer volume would add little to the effective protection of the public.” *Thompson v. Cty. of Alameda*, 27 Cal. 3d 741, 754–55 (1980); *see also Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910, 932 (2004) (“The problems of overwarning are exacerbated if warnings must be given even as to very remote risks Against the benefits that may be gained by a warning must be balanced the dangers of overwarning and of less meaningful warnings crowding out necessary warnings, the problem of remote risks, and the seriousness of the possible harm to the consumer.”) (internal citation omitted).

88. An order enjoining future enforcement of the Proposition 65 warning requirement for cancer as applied to Listed Titanium Dioxide in cosmetic and personal care products would redress the harms described above.

CLAIMS FOR RELIEF

COUNT I

(Violation of the First Amendment to the U.S. Constitution — 28 U.S.C. § 2201)

89. The foregoing Paragraphs are incorporated by reference as if set forth in full herein.

90. The Free Speech Clause of the First Amendment of the United States Constitution

provides that “Congress shall make no law . . . abridging the freedom of speech.” U.S. Const. amend. I. The Fourteenth Amendment of the United States Constitution made this proscription applicable to the States and their political subdivisions. *See id.* amend. XIV § 1.

91. In addition to providing protections against restrictions on speech, the First Amendment provides protection against the government *compelling* individuals or entities to engage in speech.

92. Under the First Amendment, laws compelling speech ordinarily receive strict scrutiny. *See Wooley v. Maynard*, 430 U.S. 705, 715-16 (1977). Laws regulating commercial speech generally receive at least intermediate scrutiny, *i.e.*, they are prohibited if they do not directly and materially advance the government’s interest, or are more extensive than necessary. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 566 (1980). And even laws that require businesses to provide information in connection with commercial transactions are permissible only if the compelled disclosure is of information that is purely factual and uncontroversial, reasonably related to a substantial government purpose, and not unjustified or unduly burdensome. *See Nat’l Inst. of Family & Life Advocates v. Becerra*, 585 U.S. ___, 138 S. Ct. 2361, 2372, 2377 (2018) (“*NIFLA*”); *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985). The Government bears the burden to show that a compelled disclosure is permissible under the First Amendment.

93. A Proposition 65-compliant cancer warning—irrespective of the specific language used—conveys to the average consumer of products intended for human use that the chemical at issue (here, Listed Titanium Dioxide) causes cancer in humans.

94. Contrary to the warning mandated by Proposition 65, there is no reliable scientific evidence that Listed Titanium Dioxide increases the risk of cancer in humans. To the contrary, independent review of animal studies and epidemiological studies suggest that there is no association between exposure to Listed Titanium Dioxide from cosmetic and personal care products and cancer in humans.

95. Nor does California “know” that Listed Titanium Dioxide causes cancer. Instead, Proposition 65 requires California to place Listed Titanium Dioxide on the list of chemicals “known to the State to cause cancer” simply because IARC determined it is a possible human carcinogen

1 based on sufficient evidence in experimental animals.

2 96. Moreover, even IARC has not said that it “knows” that exposure to Listed Titanium
3 Dioxide causes cancer in humans. Rather, it has only identified certain forms of titanium dioxide as a
4 “possible” human carcinogen based on highly suspect studies in laboratory animals. Indeed, IARC
5 concluded: “There is inadequate evidence in humans for the carcinogenicity of titanium dioxide. *See*
6 ¶ 4, *supra*.

7 97. The use of the word “known” in the compelled cancer warning for Listed Titanium
8 Dioxide is therefore misleading at best. *California Chamber of Commerce v. Council for Educ. &*
9 *Research on Toxics*, 29 F.4th 468, 479 (2022).

10 98. The Proposition 65 cancer warning requirement as applied to Listed Titanium Dioxide
11 in cosmetic products thus compels speech that is false, misleading, and factually controversial.

12 99. Because Proposition 65’s cancer warning requirement as applied to Listed Titanium
13 Dioxide in cosmetic and personal products is false, misleading, and factually controversial, it cannot
14 survive any level of constitutional scrutiny. *See Video Software Dealers Ass’n v. Schwarzenegger*,
15 556 F.3d 950, 967 (9th Cir. 2009) (“[T]he State has no legitimate reason to force retailers to affix
16 false information on their products.”). Proposition 65’s cancer warning requirement as applied to
17 Listed Titanium Dioxide in cosmetic and personal care products therefore constitutes impermissible
18 compelled speech under the First Amendment.

19 100. In the alternative, the Proposition 65 warning requirement also is unconstitutional on
20 its face. In *NIFLA*, the U.S. Supreme Court made clear that the State has the burden to show that a
21 warning is “justified” before it may compel a business to provide one consistent with the First
22 Amendment. *See* 138 S. Ct. at 2377. A Proposition 65 warning requirement is “justified” only for an
23 exposure to a listed chemical at a level that exceeds the NSRL. Proposition 65, however, reverses
24 this burden, stating that “the burden of showing that an exposure [poses no significant risk] shall be
25 on the defendant.” Cal. Health & Safety Code § 25249.10(c). The Proposition 65 warning
26 requirement is thus unconstitutional on its face because it places the burden on the *business* to
27 disprove that a warning is justified, when *NIFLA* and other U.S. Supreme Court precedent hold that it
28 is the *government’s* burden to prove that a warning is justified.

101. Plaintiff's members include entities that have already been harmed by California's requirement to provide a false, misleading, and/or highly controversial cancer warning for Listed Titanium Dioxide in cosmetic and personal care products, and will be injured further if forced to either comply with Proposition 65's compelled false warning requirement, or incur costly other burdens and face the threat of private enforcement suits or other enforcement actions.

COUNT II
(Violation of the First Amendment to the U.S. Constitution — 42 U.S.C. § 1983)

102. The foregoing Paragraphs are incorporated by reference as if set forth in full herein.

103. 42 U.S.C. § 1983 provides in relevant part that "[e]very person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceed for redress"

104. The Proposition 65 cancer warning requirement as applied to Listed Titanium Dioxide in cosmetic products compels speech that is false, misleading, and factually controversial.

105. Because Proposition 65's cancer warning requirement as applied to Listed Titanium Dioxide in cosmetic and personal products compels speech that is false, misleading, and factually controversial, it cannot survive any level of constitutional scrutiny. Proposition 65's cancer warning requirement as applied to Listed Titanium Dioxide in cosmetic products therefore constitutes impermissible compelled speech under the First Amendment.

106. In the alternative, the Proposition 65 warning requirement also is unconstitutional on its face under the First Amendment.

107. Plaintiff and its members are persons within the meaning of 42 U.S.C. § 1983 and have a right to free speech (which includes the right not to speak) under the First Amendment to the United States Constitution, as applicable to the States and their political subdivisions through the Fourteenth Amendment to the United States Constitution.

108. Plaintiff's members include entities that have already been harmed by California's

1 requirement to provide a false, misleading, and/or highly controversial cancer warning for Listed
 2 Titanium Dioxide in cosmetic products, and will be injured further if forced to either comply with
 3 Proposition 65's compelled false warning requirement, or incur costly other burdens and face the threat
 4 of private enforcement suits or other enforcement actions. Plaintiff's members also include entities
 5 that have yet not been targeted in private enforcement actions for exposures to Listed Titanium Dioxide
 6 in certain cosmetic and personal care products but—because of the widespread and FDA-approved
 7 presence of titanium dioxide in hundreds of cosmetic and personal care products on sale today in
 8 California—face a real and credible threat of being targeted in future enforcement actions.

9 109. Defendant is responsible for enforcing Proposition 65 and does so under color of state
 10 law. In addition, private enforcers under Cal. Health & Safety Code § 25249.7(d) also act under
 11 color of state law because, *inter alia*:

12 a. Private enforcement actions are authorized by state statute to be brought only
 13 “in the public interest.” *Id.* § 25249.7(d);

14 b. Private enforcers must provide notice to the Attorney General and other public
 15 prosecutors before initiating an enforcement action. *Id.* § 25249.7(d)(1);

16 c. The Attorney General screens and evaluates private enforcers' notices of
 17 prospective enforcement actions and is obligated to object to any enforcement action he believes
 18 lacks merit. *Id.* § 25249.7(e)(1)(A);

19 d. Private enforcers may initiate an enforcement action only if the Attorney
 20 General and all district attorneys and city attorneys of certain large cities have not begun prosecuting
 21 the alleged violation themselves, *id.* § 25249.7(d)(2);

22 e. The State, through the Attorney General, is authorized to review and challenge
 23 proposed settlements in private enforcement actions, *id.* § 25249.7(f); and

24 f. Seventy-five percent of any penalties assessed in private enforcement actions
 25 go to the State treasury, *id.* § 25249.12.

26 110. In other words, private enforcers of Proposition 65 stand in the shoes of the State when
 27 enforcing the Proposition 65 statute. The activities of “persons in the public interest” are both directly
 28 and indirectly regulated, monitored, controlled, and guided by the California Attorney General.

PRAYER FOR RELIEF

WHEREFORE, excluding Proposition 65 claims on Listed Titanium Dioxide that are currently pending in state court, Plaintiff demands judgment against Defendant as follows:

1. A declaration, pursuant to 28 U.S.C. § 2201 and/or 42 U.S.C. § 1983, that the Proposition 65 warning requirement for titanium dioxide (airborne, unbound particles of respirable size), Cal. Health & Safety Code § 25249.6, as applied to cosmetic and personal care products, violates the First Amendment of the United States Constitution.

2. In the alternative, a declaration, pursuant to 28 U.S.C. § 2201 and/or 42 U.S.C. § 1983, that the Proposition 65 warning requirement, Cal. Health & Safety Code § 25249.6, on its face violates the First Amendment of the United States Constitution.

3. Prospective preliminary and permanent injunctions, pursuant to 42 U.S.C. § 1983 and other applicable law, prohibiting Defendant or any of its officers, employees, or agents, and all those in privity with and/or acting in concert with those entities or individuals (including private enforcers of Proposition 65 under Cal. Health & Safety Code § 25249.7(d)), from enforcing or threatening to enforce in the future the Proposition 65 warning requirement for cancer with respect to titanium dioxide (airborne, unbound particles of respirable size) in cosmetic and personal care products.

4. All costs, attorneys' fees, and expenses that Plaintiff reasonably incurs, *see* 42 U.S.C. § 1988; and

5. Such other and further relief as this Court deems just and proper.

Dated: May 26, 2023

Respectfully submitted,

By: /s/ Trenton H. Norris
Trenton H. Norris (CA Bar No. 164781)
David M. Barnes (CA Bar No. 318547)
Alexander Tablan (CA Bar No. 346309)
HOGAN LOVELLS US LLP
Four Embarcadero Center, 35th Floor
San Francisco, CA 94111
Tel: (415) 374-2300
trent.norris@hoganlovells.com

*Attorneys for Plaintiff
Personal Care Products Council*